

delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

## **PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS**

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (41 U.S.C. 216, 262, 263, 263a, 264).

2. Section 610.64 is revised to read as follows:

### **§ 610.64 Name and address of distributor.**

The name and address of the distributor of a product may appear on the label provided that the name, address, and license number of the manufacturer also appears on the label and the name of the distributor is qualified by one of the following phrases: "Manufactured for \_\_\_\_\_", "Distributed by \_\_\_\_\_", "Manufactured by \_\_\_\_\_ for \_\_\_\_\_", "Manufactured for \_\_\_\_\_ by \_\_\_\_\_", "Distributor: \_\_\_\_\_", or "Marketed by \_\_\_\_\_". The qualifying phrases may be abbreviated.

Dated: October 28, 1996.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 96-28530 Filed 11-5-96; 8:45 am]

BILLING CODE 4160-01-F

## **DEPARTMENT OF TRANSPORTATION**

### **Federal Highway Administration**

#### **23 CFR Part 640**

[FHWA Docket No. 95-19]

RIN 2125-AD62

#### **Certification Acceptance**

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Final rule.

**SUMMARY:** The FHWA, in an interim final rule published in the Federal Register on September 13, 1995, adopted a policy that allows State highway agencies (SHAs) to use the certification acceptance (CA) procedures for non-Interstate projects to supplement the administrative flexibility provided in the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Public Law 102-240, 105 Stat. 1914. This final rule contains one minor modification to the CA policy to

clarify that certain project actions do not require FHWA approval.

**EFFECTIVE DATE:** This regulation is effective December 6, 1996.

**FOR FURTHER INFORMATION CONTACT:** Mr. Félix Rodríguez-Soto, Federal-Aid and Design Division, Office of Engineering, (202) 366-1564, or Mr. Wilbert Baccus, Office of the Chief Counsel, (202) 366-0780, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:** On September 13, 1995, the FHWA published an interim final rule (60 FR 47480) establishing the procedures to be followed by SHAs for the processing of transportation projects under CA. A 90-day period for agencies, firms, or individuals to provide comments was allowed. The changes made to the CA regulation by the interim final rule are discussed below.

The interim final rule eliminated the mandatory requirement for evaluation of the CA program in each State every four years. The requirement that the State's laws, regulations, directives, and standards must accomplish the policies and objectives contained in title 23, U.S.C., was retained. In keeping with the streamlining effort, specific requirements of the States for CA, including reports, were deleted because title 23, U.S.C., requirements will be subject to periodic changes. The revised CA regulation provided that States may be requested to furnish reports and information at the discretion of the FHWA. All references to the Secondary Road Plan (SRP) were removed because the SRP program was eliminated under the ISTEA restructuring.

The CA procedures were not completely eliminated because, even in light of the additional flexibility provided by the ISTEA and, in particular, 23 U.S.C. 106, National Highway System (NHS) projects may be administered under CA and may not be administered under 23 U.S.C. 106. In addition, some SHAs continue to use CA notwithstanding the more flexible options available under 23 U.S.C. 106.

#### **Discussion of Comments**

This section addresses the comments received on the interim final rule. The FHWA received comments from six SHAs and one organization.

#### **General Comments**

Five States supported the regulation (two as published in the interim final rule and three with minor modifications).

One State commented that CA has worked successfully in that State. This State was concerned that partial or full revocation by the FHWA of a State's CA plan could be based on process review findings which may not be part of a State's CA plan. This State also recommended that the final rule establish the nature of the process reviews and other evaluations and that an appeal process be established in case of partial or full revocation. In response, the FHWA maintains that the revisions to the CA regulation were meant to update the regulation to conform to new program provisions, to simplify the existing regulation by eliminating unnecessary and prescriptive requirements, and to allow for the use of process reviews which are already the primary form of program oversight by the FHWA. The use of process reviews is not unique for CA projects and the FHWA's methods of conducting process reviews should be familiar to SHA's. The States' right to appeal was not changed by the interim final rule.

The one organization that commented contends that an interim rule, without previous issuance of a notice of proposed rulemaking, inhibits public participation and debate on a proposed regulation and causes reliance by States on interim policy which may subsequently change as result of public comments. In addition, it alleges that the supplementary information section in the preamble to the interim rule, as published in the Federal Register (60 FR 47480), is inaccurate when it characterizes a State CA procedure as legally acceptable if it merely "aims to comply" with title 23, U.S.C., policies, and that "streamlining" of CA is a full retreat from Federal monitoring of the use of Federal highway construction dollars.

In response to this organization's contention concerning the use of an interim rule, the FHWA maintains that the interim rule merely updated the CA regulation, removed unnecessary prescriptive requirements as part of the government regulatory review effort, provided more administrative flexibility in the use of the regulation, and did not impose any additional restrictions on the public. The FHWA intends that a State accomplish title 23, U.S.C., policies through its CA procedures. The FHWA also maintains that the "streamlining" is not a "retreat" from FHWA oversight, but an acknowledgment that the use of process reviews and evaluations is the current and primary method of project oversight by the FHWA and that it accomplishes the same objective as the former project specific reviews. In addition, the

interim rule with request for comments allowed SHAs who choose to participate in the CA program and others adequate opportunity to comment on the interim rule. The FHWA, based on an analysis of public comments received, has re-examined its decision to go forward with the interim final rule as the basis for CA and has determined that an interim rule was the appropriate choice in this case. The FHWA also determined that prior notice and opportunity for comment were not required under the Department of Transportation's Regulatory Policies and Procedures because it was not anticipated that such action would result in the receipt of useful information.

#### *Specific Comments*

No specific comments were received for §§ 640.107, 640.109, 640.111, 640.115, and 640.117 and these sections are unchanged.

Section 640.113 is being revised to conform to comments received. Comments from the States included: (1) one State recommended removal of paragraph (e) to be consistent with the removal of 23 CFR 140, Subpart A, formerly titled "Reimbursable Vouchers"; and (2) two States suggested removal of the reference to FHWA approval of exceptions in paragraph (e) to be consistent with 640.113(b) which only requires the States to justify and document the approval of the exceptions. In the final rule, the requirements of FHWA approval of exceptions and the submission of final vouchers to the FHWA in paragraph (e) are removed and the remaining text in paragraph (e) is merged into paragraph (d). Paragraph (f) is redesignated as paragraph (e) in the final rule.

#### *Rulemaking Analysis and Notices*

#### *Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures*

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of Department of Transportation Regulatory Policies and Procedures. As stated, this regulation merely streamlines and updates the current CA regulation by giving added flexibility to the States in their use of CA. It is anticipated that the economic impact of the rulemaking will be minimal; therefore, a full regulatory evaluation is not required.

#### *Regulatory Flexibility Act*

In compliance with the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C.

601-612), the FHWA has evaluated the effects of this rule on small entities. Based on the evaluation, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. The FHWA made this determination based on the fact that the final rule for CA is an update of a current regulation and will provide greater flexibility in using the CA alternate procedures in the administration of projects consistent with the provisions of ISTEA.

#### *Executive Order 12612 (Federalism Assessment)*

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. This rule does not impose additional costs or burdens on the States, including the likely source of funding for the States nor does it affect the ability of the States to discharge traditional State government functions. The intent of this rule is to provide the States with additional administrative flexibility in the use of the regulation.

#### *Executive Order 12372 (Intergovernmental Review)*

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

#### *Paperwork Reduction Act*

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

#### *National Environmental Policy Act*

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

#### *Regulation Identification Number*

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this

document can be used to cross reference this action with the Unified Agenda.

#### *List of Subjects in 23 CFR Part 640*

Government procurement, Grant programs-transportation, Highways and roads.

Issued on: October 28, 1996.

Rodney E. Slater,

*Federal Highway Administrator.*

In consideration of the foregoing, the interim rule published at 60 FR 47480 on September 13, 1995, title 23, Code of Federal Regulations, Part 640 is adopted as a final rule with the following changes:

#### **PART 640—CERTIFICATION ACCEPTANCE**

1. The authority citation continues to read as follows:

Authority: 23 U.S.C 101(e), 117, and 315; 49 CFR 1.48.

2. Section 640.113 is amended by revising paragraph (d), by removing paragraph (e), and by redesignating paragraph (f) as paragraph (e) to read as follows:

#### **§ 640.113 Procedures.**

\* \* \* \* \*

(d) The FHWA may accept projects based on inspections of a type and frequency necessary to ensure the projects are completed in accordance with appropriate standards. The State is to notify the FHWA when a project is complete and/or ready for such inspection and will certify that the plans, design, and construction for the project were in accord with the laws, regulations, directives, and standards contained in the State certification or such project exceptions as were approved by the State.

\* \* \* \* \*

[FR Doc. 96-28577 Filed 11-5-96; 8:45 am]

BILLING CODE 4910-22-P

#### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Part 52**

[NV-029-0001; FRL-5644-8]

#### **Clean Air Act Reclassification; Nevada-Clark County Nonattainment Area; Carbon Monoxide**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA finds that the Clark County, Nevada carbon monoxide (CO) nonattainment area has met the criteria